

For: ENCAPSULATED MULTIFUNCTIONAL BIOLOGICALLY ACTIVE FOOD
COMPONENT; PROCESS FOR ITS PRODUCTION AND ITS USE

Declaration of Prof. Dr. Benno Kunz

Under 37 C.F.R. §1.132

Honorable Commissioner for
P.O. Box 1450
Alexandria, VA 22313-1450

I, BENNO KUNZ declare and state that:

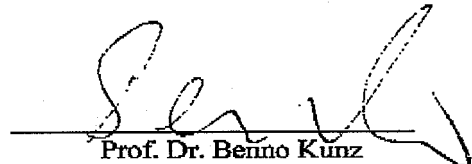
1. I am a resident of the Federal Republic of Germany.
2. I am a citizen of the Federal Republic of Germany.
3. I am an Engineer having received a university degree in engineering (equivalent to MS in engineering) from the Technical University of Dresden and a Dr.-Ing degree from the same university in Germany, in 1965-1970, respectively 1970-1973. Since 1989 I have a chair of Food Technology and Food Biotechnology at the University of Bonn, Germany. I'm executive director of the Institute of Food Technology of Bonn University and I was dean of the agricultural faculty from 1994 to 1996. At the same time, my institute has been under numerous research agreements with industrial and institutional partners from various countries.
4. I have been giving lectures in biotechnology, food technology, and process engineering since 1975. I'm doing research in the area of microencapsulation. Some of my institute publications in this field are:
 1. Chancen und Grenzen der Mikroverkapselung in der modernen Lebensmittelverarbeitung. CIT (75) 9 in press 2003 [Chances and limits of microencapsulation in modern food technology]
 2. Influence of Different Capsule Materials on the Physiological Properties of Microencapsulated Lactobacillus acidophilus. Diss. Bonn 2003 in press
 3. Stabilization of Probiotics. Dechema Jahrestagung der Biotechnologen, München 2003 [DECHEMA annual meeting of biotechnologists]Since 1998 my institute together with two companies is participating in a project for microencapsulation of bioactive substances. The project is partially funded by the federal Government.
5. I consider myself qualified by my knowledge of biotechnology, bioprocess engineering, food technology, and food biotechnology and by my years of experience in these technical fields for more than 20 years.
6. I am a co-inventor of the above-captioned United States Patent Application and therefore have personal knowledge of its subject matter.
7. I have read and understand the Official Action mailed on April 3, 2003 ("the Office Action").

8. I understand that claims 1 -3, and 5- 10 stand rejected as being unpatentable over Ueda et al.
9. I understand that claims 1, 2, 6 and 8-10 stand rejected as being unpatentable over Ghani (US 6, 120, 811).
10. I understand that claims 11-19 stand rejected as being unpatentable under 35 U.S.C. §103(a) over Ghani in view of Ardaillon et al. and Hessel et al.
11. It is the Examiner's position that the illustration supplied with Applicant's last response as Appendix A, shows that the particle is round, with most likely fiber particles inside which seem to be coated with a material different than the outside coating. The Examiner notes that there is actually a break in the coating at the left side of the picture.
12. The picture of Appendix A of Applicant's last response, which is again attached to this Declaration, was actually taken in my laboratories under my supervision on a material prepared as described in Example 1 of the Application. It shows microorganisms embedded into some core material and surrounded by a capsule material which is different from the core material. The "streak" interpreted by the Examiner as a "break" in the capsule is nothing but an accidental effect caused by mechanical stress during the encapsulation process. This "streak" is most likely a pleat in the shell and has no influence, whatsoever, on the integrity of the capsule and its functionality as a stable barrier between the outside and the inside of the capsule as proven by a hydrolysis test (c.f. para 13 below).
13. On the other hand granules according to Ghani do not possess a stability which is comparable to the present invention. Ghani discloses in the background section of the disclosure that "these microgranules preferable are dispersible or blendable with food (i.e. baking) ingredients and disintegrate rapidly in an aqueous environment to provide quick availability of the enzyme." [Ghani at col. 1, ln. 48-52]. Quite contrary the microcapsules according to the present invention protect the bioactive substances in an aqueous environment up to the intestinal tract [c.f. present specification, paragraph bridging p. 13/14]. Hence, it follows that there is a significant difference between Ghani's microgranules and the microcapsules according to the present invention.
14. The difference between the granules according to Ghani and the capsules according to the present invention becomes apparent when the release rates are compared
Ghani: rapid disintegration in aqueous environment
Present invention: stable in all stages from the processing (i.e. manufacture) to the intestinal tract
15. Moreover, I would like to emphasize that capsules are different from granules in general. Granules are characterized by a more or less homogenous distribution of

the granule components. In Capsules, on the other hand, the core, e.g. the bioactive substance (probiotic microorganisms) is completely wrapped by the shell; the different components (core/shell) are heterogeneously distributed. This difference in the spatial arrangement of the components can lead to totally different physical behavior of an otherwise (here chemical) identical composition. This is impressively shown by the difference in hydrolytical stability of Ghani's granules and the capsules according to the present invention.

16. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statement may jeopardize the validity of the application or any patent issued thereon.

03.09.2003
Date


Prof. Dr. Benno Kunz

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